



June 1, 2001

Ms. Kimberly Topper
Center for Drug Evaluation Research
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Topper:

I am writing you concerning the meeting of The Aesthetics and Life Support Drug Advisory Committee scheduled for June 14 and 15 at the Holiday Inn in Gatorsville, Maryland. I just wanted to voice my concern over the potential loss of the ability to prescribe opioid analgesics to individuals who suffer with chronic pain of a nonmalignant etiology.

In my family practice I have had extensive background with chronic pain and pain management for people from nonmalignant origins. I have found opioids to be extremely affective and efficient in improving the quality of life and reducing pain in individuals who have suffered for many years due to under treatment of their pain. I realize that there has been significant concern over the drug abuse and diversion that has occurred recently but all major studies to date indicate that the problem falls into a category between 2 and 6% of the general population as a whole. My concern is for the 94-98% of the population who has true chronic pain and who statistically has been shown to be under medicated. These individuals, when there problems are approached in a logical and straight forward way, have been found to be treated extremely effective with the use of opioid analgesics.

Thank you for your interest in the treatment of chronic pain and for the FDA's diligence and concern, but I wanted my voice to be heard concerning the beneficial aspects of the class of drugs and the treatment of this significant problem. Please feel free to contact my office with any information or questions that you may have concerning the use of the opioid drugs in our practice.

Back Creek Family Practice Center
7119 Bent Mountain Road * Roanoke, VA 24018 * 540/989-0757

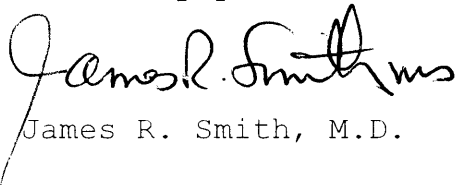
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I look forward to receiving information and reviewing the outcome of your meetings on June 14 and 15.

Sincerely yours,

A handwritten signature in cursive script that reads "James R. Smith". The signature is written in black ink and is positioned above the printed name.

James R. Smith, M.D.

JRS/cls